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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,038	01/09/2004	Avram Reuben Gold	2111-040037	7887

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
08/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/755,038	GOLD, AVRAM REUBEN	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,8-12,16,17,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8-12,16,17,19,20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/07 has been entered.

Specification

Amendment to the specification filed on 5/21/07 is acknowledged, and will be entered.

Response to Amendment

The declaration under 37 CFR 1.132 filed 5/21/07 is sufficient to overcome the rejection of claims 1,5,6,7,11,12, and 15-18 based upon 35 USC 103 (a) over Pantino in view of Thornton and rejection to claims 1,4-12, and 15-20 under 35 USC 112 first paragraph.

Response to Arguments

Applicant's arguments, see remarks, filed 5/21/07, with respect to the rejection(s) of claim(s) 1,5,6,7,11,12, and 15-18 under 35 USC 103 (a) for obviousness over US 6,769,910 to Pantino in view of Thornton have been fully considered and are persuasive. Therefore, the

rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Thornton US 5,945,048.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,5,6,11,12,16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Threnton US 6,769,910 B1.

As to claim 1, Thornton teaches a method of treating functional somatic syndromes comprising the steps of:

determining whether a patent suffers from inspiratory airflow limitation during sleep (the device of Thornton is for treating breathing disorders, i.e. patient suffering from obstructive sleep apnea and snoring, see col.3, lines 10 and 11. It is well know in that art that upper airway obstruction is one of the causes of sleep apnea, where disruption of sleep happens because airway muscles tighten, hence creating obstruction of the breathing passage. Thus the device of Thornton is used by patients who are diagnosed with (or "determined to suffer from") inspiratory airflow limitation during sleep.);

identifying such a patient as having a functional somatic syndrome (Thornton teaches his device is for treating snoring, obstructive sleep apnea, or other breathing disorders, see col. 3, lines 10 and 11. Applicant on page 4 paragraphs [13]-[17] and page 6 paragraph [20] of the specification lists disorders/diseases that are considered functional somatic syndrome. This list includes sleep apnea, snoring, and other breathing disorders (i.e. upper airway resistance syndrome) that can be treated by Thornton's device. Thus, Thornton teaches a device that is capable of providing treatment for a functional somatic syndrome (combined symptoms of other breathing disorders). Furthermore, it is known in the art that diagnosis follows treatment, thus, a physician has to identify or diagnose a patent with functional somatic syndrome prior to prescribing treatment with Thornton's device); and

treating such a patient with an upper airway stabilization technique (via apparatus of fig.1a);

wherein treating such a patient with an airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy (see fig.1A, 88).

As to claim 5, Threnton teaches the method as claimed in claim 1, wherein the positive airway pressure therapy is selected from the group consisting of: continuous positive airway pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure (fig.1a, 88).

As to claim 6, Threnton teaches the method as claimed in claim 1, wherein identifying a patient as having a functional somatic syndrome includes identifying a symptom of the functional somatic syndrome, wherein the symptom is selected from the group consisting of: chronic fatigue, irritable bowel, migraine headaches, tension headaches, temporomandibular

joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, depression, orthostatic syncope, alpha-delta sleep (Threnton teaches a device that can provide treatment of sleep apnea, snoring, and other breathing disorders, see col.3, lines 10 and 11, thus Threnton teaches claimed "muscle pain" and "muscle tenderness" as symptoms of upper airway obstruction syndrome).

As to claim 11, Threnton lacks the method as claimed in claim 1, wherein the functional somatic syndrome is selected from the group consisting of: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, and restless leg/periodic limb movement syndrome. However, migraine headaches and/or tension headaches can be caused by the obstruction of upper airway muscle. Thus, during the diagnosis of breathing disorders, migraine headaches and /or tension headaches can be documented as symptoms of breathing disorders syndrome. Thus, Trenton's teaching of "other breathing disorders" can include migraine headaches and tension headaches.

As to claim 12, Threnton teaches a method of treating functional somatic syndromes comprising the steps of:

determining whether a patient suffers from inspiratory airflow limitation during sleep (the device of Thornton is for treating breathing disorders, i.e. patient suffering from obstructive sleep apnea and snoring, see col.3, lines 10 and 11. It is well know in that art that upper airway obstruction is one of the causes of sleep apnea, where disruption of sleep happens

because airway muscles tighten, hence creating obstruction of the breathing passage. Thus the device of Thornton is used by patients who are diagnosed with (or "determined to suffer from") inspiratory airflow limitation during sleep.);

identifying such a patient as having one or more symptom of a functional somatic syndrome (Thornton teaches his device is for treating snoring, obstructive sleep apnea, or other breathing disorders, see col. 3, lines 10 and 11. Applicant on page 4 paragraphs [13]-[17] and page 6 paragraph [20] of the specification lists disorders/diseases that are considered functional somatic syndrome. This list includes sleep apnea, snoring, and other breathing disorders (i.e. upper airway resistance syndrome) that can be treated by Thornton's device. Thus, Thornton teaches a device that is capable of providing treatment for a functional somatic syndrome (combined symptoms of other breathing disorders). Furthermore, it is known in the art that diagnosis follows treatment, thus, a physician has to identify or diagnose a patent with functional somatic syndrome prior to prescribing treatment with Thornton's device); and

treating such a patient with an airway stabilization technique (via apparatus of fig. 1a);

wherein treating such a patient with an airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy (see fig.1a, 88).

As to claim 16, Threnton teaches the method as claimed in claim 12, wherein the positive airway pressure therapy is selected from the group consisting of: continuous positive airway pressure, bi-level positive airway pressure, and auto-titrating positive airway pressure (see fig.1a, 88).

As to claim 17, Threnton teaches the method as claimed in claim 12, wherein the symptom of the functional somatic syndrome is selected from the group consisting of: chronic

fatigue, irritable bowel, a migraine headache, a tension headache, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, headaches, depression, orthostatic syncope, alpha-delta sleep (Threnton teaches a device that can provide treatment of sleep apnea, snoring, and other breathing disorders, see col.3, lines 10 and 11, thus Threnton teaches claimed "muscle pain" and "muscle tenderness" as symptoms of upper airway obstruction syndrome).

Claims 8,9,19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Threnton US 6,769,910 B1 in view Knowallik et al US 6,752,766 B2.

As to claim 8, Threnton teaches the claimed method step as applied to claim 1. Threnton however lacks the method as claimed in claim 1, further comprising the step of categorizing a patient who has an inspiratory airflow limitation during sleep of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient. However, Kowallik teaches claimed step (see col.5, lines 12-20, col.6, lines 10-40, and col.8, lines 7-11) for the purposes of detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA (col. 3, lines 53-60). Therefore, it would have been obvious to one of ordinary skill in the art to include means for categorizing patients by type of respiratory disorder because it would have provided a means for detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA as taught by Kowallik.

As to claim 9, Kowallik teaches the method as claimed in claim 1, further comprising the step of categorizing a patient who has an inspiratory airflow limitation during sleep of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient (see col.5, lines 12-20 and col.6, lines 10-62).

As to claim 19, Threnton lacks the method as claimed in claim 12, further comprising the step of categorizing a patient who has an inspiratory airflow limitation .of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient. However, Kowallik teaches claimed step (see col.5, lines 12-20, col.6, lines 10-40, and col.8, lines 7-11) for the purposes of detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA (col. 3, lines 53-60). Therefore, it would have been obvious to one of ordinary skill in the art to include means for categorizing patients by type of respiratory disorder because it would have provided a means for detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA as taught by Kowallik.

As to claim 20, Kowallik teaches the method as claimed in claim 12, further comprising the step of categorizing a patient who has an inspiratory airflow limitation of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient (see col.5, lines 12-20 and col.6, lines 10-62).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Threnton US 6,769,910 B1 in view of Bennett US 5,378,686.

As to claim 10, Threnton lacks the method as claimed in Claim 1, further comprising observing alpha-delta sleep of such a patient to diagnose the fictional somatic syndrome. However, Bennett teaches observing alpha-delta sleep of such a patient to aid in diagnosing the functional somatic syndrome. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include monitoring patients for alpha-delta sleep to diagnose a functional somatic syndrome as taught by Bennett because it would have aided in the diagnosing more serious illness which may also exhibit sleep disorder symptoms as taught by Bennett.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shumaya Ali 8/2/2007

Shumaya B. Ali
Examiner
Art Unit 3771

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8/3/07